

Application Serial No.: 09/642,242  
 Rule 1.111 Amendment  
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### Amendments to the Claims:

Please amend the claims as indicate below.

2. (Amended) A pharmaceutical formulation for oral or topical administration ~~including~~ comprising

a) ~~one or more cyclospines~~ 0.1 to 30.0 % by weight of one or more hydrophobic active ingredients;

b) ~~5 to 50% of one or more compounds selected from~~ 0.1 to 60.0 % by weight of one or more gelators comprising polyglycerol esters of fatty acids of formula (1)



wherein n is an integer from 4 to 13 and R is H or  $\text{CO}_2\text{R}'$  wherein  $\text{R}'$  is  $\text{C}_{8-22}$  saturated, unsaturated or hydroxylated alkyl and wherein at least one group R is not hydrogen, having an HLB value not less than 10;

c) ~~5 to 50% of one or more compounds 0.1 to 60.0 % by weight of one or more gel-creating substances selected from polyglyceryl-3-esters of oleic acid, having an HLB value not greater than 2; polyglycerol esters of fatty acids and/or unsaturated fatty acids of formula (2)~~



wherein n is an integer from 0-10 and R is H or  $\text{CO}_2\text{R}''$  wherein  $\text{R}''$  is  $\text{C}_{8-22}$   ~~$\text{C}_{12-18}$~~  saturated, unsaturated or hydroxylated alkyl, and wherein at least one group R is not hydrogen;

d) ~~5 to 50% of one or more compounds~~ 1.0 to 60 % by weight of one or more co-gelator substances selected from the group consisting of triglyceride macrogol glycerol esters, partial glycerides of fatty acids and macrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of the substances ranges between 50 to 150 mols and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1;

e) 5.0 to 30% by weight of one or more  $\text{C}_2$  to  $\text{C}_4$  alcohols;

wherein the above percentages are selected the total 100%;

and wherein upon dilution with water 1:1 by volume the viscosity of a formulation ~~increases by at least 5 times in comparison to the undiluted composition~~ the formulation forms a dispersion of ~~non-spherical~~ polymorphous gel particles having a dimension of 0.2 to 500  $\mu\text{m}$ .

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25. (Amended) A formulation as claimed in ~~claim 2~~ any preceding claim, wherein component a) is selected from cyclosporins cyclosporin A, cyclosporin D or cyclosporin G, wherein the ratio of components a:c + e is 1.001:1 to 1.5:1.

27. (Amended) A formulation as claimed in ~~claim 2~~ any preceding claim, wherein component a) is selected from taxanes, especially docetaxel or paclitaxel, wherein the ratio of components a:c + e is 0.001:1 to 1.5:1.

29. (Amended) A formulation as claimed in ~~claim 2~~ any preceding claim, wherein component a) includes at least one compound selected from the group comprising cyclosporins and ~~further~~ at least one compound selected from the group comprising taxanes.

31. (Cancelled)

33. (Amended) The ~~A pharmaceutical~~ dosage form of ~~claim 31~~ comprising a formulation of claim 2 in combination with a pharmaceutically acceptable excipient, wherein the dosage form is a liquid dosage form.

34. (Amended) The ~~A pharmaceutical~~ dosage form of ~~claim 31~~ comprising a formulation of claim 2 in combination with a pharmaceutically acceptable excipient, wherein the dosage form is a gelatin capsule.

35. (New) A pharmaceutical formulation as claimed in claim 2, wherein the ratio of a:c and/or a:e is in the range 0.001:1 to 10:1.

36. (New) A formulation as claimed in claim 2, wherein R' is C<sub>16-18</sub> saturated or unsaturated alkyl.

37. (New) A formulation as claimed in claim 2, wherein R' is selected from the group consisting of oleates, linoleate stearate, linolate, myristate, laurate and mixtures thereof.

38. (New) A formulation as claimed in claim 2, wherein component b) is selected from polyglyceryl-10-esters of fatty acids.

39. (New) A formulation as claimed in ~~any preceding claim~~, wherein component d) is macrogol glycol hydrogenated castor oil.

40. (New) A formulation as claimed in any preceding claim, wherein component b) is selected from polyglyceryl-10-esters of oleic acid; component c) is selected from polyglyceryl-3-esters of oleic acid; and component d) is macrogol (1760) glycerol hydrogenated castor oil.

41. (New) A formulation as claimed in any preceding claim, further comprising excipients to modify the physical, chemical, microbial stability, organoleptic or physical processing properties of the formulation.

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42. (New) A method for making a pharmaceutical formulation for oral or topical administration comprising

- a) 0.1 to 30.0 % of one or more hydrophobic active ingredients;
- b) 0.1 to 60.0 % of one or more gelators comprising polyglycerol esters of fatty acids of formula (1)



wherein  $n$  is an interger from 4 to 13 and  $R$  is  $H$  or  $\text{COR}'$  wherein  $R'$  is  $\text{C}_{8-22}$  saturated, unsaturated or hydroxylated alkyl and wherein at least one group  $R$  is not hydrogen, having an HLB value not less than 10;

- c) 0.1 to 60.0 % of one or more gel-creating substances selected from polyglyceryl-3-esters of oleic acid, having an HLB value not greater than 9;
- d) 1.0 to 60 % of one or more co-gelator substances selected from the group consisting of triglyceride macrogol glycerol esters, partial glycerides of fatty acids and macrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of the substances ranges between 50 to 150 mo's and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1;

- e) 5.0 to 30% of one or more  $\text{C}_2$  to  $\text{C}_4$  alcohols;

wherein the above percentages are selected the total 100%;

and wherein upon dilution with water the formulation forms a dispersion of polymorphous gel particles having a dimension of 0.2 to 500  $\mu\text{m}$ .

43. (New) A method as claimed in claim 42, wherein the ratio of a:c and/or a:e is in the range 0.001:1 to 10:1.

44. (New) A method as claimed in claim 42, wherein  $R'$  is  $\text{C}_{16-18}$  saturated or unsaturated alkyl.

45. (New) A method as claimed in claim 42, wherein  $R'$  is selected from the group consisting of oleates, linoleate stearate, linolate, myristate, laurate and mixtures thereof.

46. (New) A method as claimed in claim 42, wherein component b) is selected from polyglyceryl-10-esters of fatty acids.

47. (New) A method as claimed in any preceding claim, wherein component d) is macrogol glycol hydrogenated castor oil.

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48. (New) A method as claimed in any preceding claim, wherein component b) is selected from polyglyceryl-10-esters of oleic acid; component c) is selected from polyglyceryl-3-esters of oleic acid; and component d) is macrogol (1760) glycerol hydrogenated castor oil.
49. (New) A method as claimed in any preceding claim, further comprising excipients to modify the physical, chemical, microbial stability, organoleptic or physical processing properties of the formulation.
50. (New) A method as claimed in any preceding claim, wherein component a) is selected from cyclosporins cyclosporin A, cyclosporin D or cyclosporin G, wherein the ratio of components a:c + e is 1.001:1 to 1.5:1.
51. (New) A method as claimed in any preceding claim, wherein component a) is selected from taxanes, especially docetaxel or paclitaxel, wherein the ratio of components a:c + e is 0.001:1 to 1.5:1.
52. (New) A method as claimed in any preceding claim, wherein component a) includes at least one compound selected from the group comprising cyclosporins and at least one compound selected from the group comprising taxanes.

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